Translation





PCT

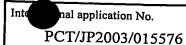
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03-074-PCT	FOR FURTHER	ACTION	See Form PCT/IPEA/416	
International application No.	International filing	iate (day/month/year)	Priority date (day/month/year)	
PCT/JP2003/015576		2003 (05.12.2003)	05 December 2002 (05.12.2002)	
International Patent Classification (IPC) or national classification and IPC A61K 31/216, 31/737, 31/78, 35/80, A61P 19/08, 19/10, 43/00 // C08B 37/00				
Applicant				
	TAKARA	A BIO INC.		
 This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 				
2. This REPORT consists of a total of _	6 sheets	s including this seven sh		
This report is also accompanied by Al	NEXES, comprising	o, merading this cover sh	eet.	
a. (sent to the applicant and t			sheets, as follows:	
sheets of the descri and/or sheets conta Administrative Inst		drawings which have bee uthorized by this Author	en amended and are the basis of this report ity (see Rule 70.16 and Section 607 of the	
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.				
b. (sent to the Internationa	l Bureau only) a	total of (indicate type	e and number of electronic carrier(s))	
readable form only, as indi Administrative Instructions	cated in the Suppler	ining a sequence listing nental Box Relating to	and/or tables related thereto, in computer Sequence Listing (see Section 802 of the	
4. This report contains indications relating	g to the following ite	ems:		
Box No. I Basis of the repo	rt			
Box No. II Priority				
Box No. III Non-establishme	nt of opinion with re	gard to novelty inventiv	e step and industrial applicability	
Box No. IV Lack of unity of		g ve se se versy, inventiv	o stop and industrial applications	
Box No. V Reasoned statement under Article 35(2) with regard to povelty, inventive step or industrial and live live.				
Box No. VI Certain documents cited				
		nlication		
Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application				
Date of submission of the demand		Date of completion of t	his report	
22 March 2004 (22.03.2004)		09 Ju	ily 2004 (09.07.2004)	
Name and mailing address of the IPEA/JP		Authorized officer		
Facsimile No.		Telephone No.		

INTERNATIONAL PRELIMARY REPORT ON PATENTABILITY



Box N	o. I	Basis of the report
1. With	regard	to the language, this report is based on the international application in the language in which it was filed, unless
	This whic	report is based on translations from the original language into the following language, the is language of a translation furnished for the purpose of:
		international search (under Rules 12.3 and 23.1(b))
		publication of the international application (under Rule 12.4)
		international preliminary examination (under Rules 55.2 and/or 55.3)
		(
2. With furni	are not	to the elements of the international application, this report is based on (replacement sheets which have been the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" attenuational application as originally filed/furnished
一	_	scription:
	pages	·
	pages'	, as originally filed/furnished
	pages'	received by this Authority on received by this Authority on
	the cla	
		iiiis.
	pages	, as originally filed/furnished
	pages*	, as amended (together with any statement) under Article 19
	pages*	leceived by this Authority on
 1	Papes	received by this Authority on
	the dra	wings:
	pages	, as originally filed/furnished
	pages*	received by this Authority on
	pages*	received by this Authority on
	a seque	ence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3.	The am	endments have resulted in the cancellation of:
		he description, pages
		he claims. Nos.
	=	
	片.;	ne drawings, sheets/figs
	片 "	ne sequence listing (specify):
	a:	ny table(s) related to sequence listing (specify):
	Rule 70	port has been established as if (some of) the amendments annexed to this report and listed below had not been since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (2.2(c)). The description, pages
	4 applie	25, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

Inte	hal application No.	
	PCT/JP03/15576	

Box No. IV	Lack of unity of invention
1 I	response to the invitation to restrict or pay additional fees the applicant has:
	restricted the claims.
	paid additional fees.
	paid additional fees under protest.
	neither restricted nor paid additional fees.
2. Thi	s Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, to invite the applicant to restrict or pay additional fees.
3. This Auth	ority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
	plied with.
⊠ not o	complied with for the following reasons:
medicine cactive ingrof compou	cal purposes themselves such as enhancing osteogenic protein production or promoting s are merely publicly known. In view of this point, claims 1-11 include an invention of a ontaining acidic saccharides, polyacrylic acid, chlorogenic acid, or alga-origin extract as the edient. However, in this technical field, the above four ingredients do not belong to a group nds recognized as a group; nor do they have a common special technical feature. Therefore, tional application does not meet the requirement of unity of invention.
Also, technical n	there is no other matter that is common to all of the claims and is considered as a special latter; therefore, the number of inventions included in the present application is four.
•	
	'
4. Consequent	ly, this report has been established in respect of the following parts of the international application:
	all parts.
	the parts relating to claims Nos
Form PCT/IPE	A/409 (Roy No. IV) (January 2004)

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applic citations and explanations supporting such statement			ial applicability;
ty (N)	Claims		YES
	Claims	1-11	NO
ive step (IS)	Claims		YES
	Claims	1-11	МО
rial applicability (IA)	Claims	1-11	YES
	Claims		NO
	citations and explana by (N) ive step (IS)	citations and explanations supporting such stater (y (N) Claims Claims ive step (IS) Claims Claims claims Claims Claims	citations and explanations supporting such statement (y (N) Claims Claims 1-11 ive step (IS) Claims Claims 1-11 rial applicability (IA) Claims 1-11

2. Citations and explanations (Rule 70.7)

Document 1: JP, 7-109222, A (Maruha Corp.), April 25, 1995 (04.25.95)

Document 2: JP, 2002-226380, A (Maruho K.K.), August 14, 2002 (08.14.02)

Document 3: JP, 6-22728, A (Asahi Chemical Industry Co., Ltd.), February 1, 1994 (02.01.94)

Document 4: JP, 10-53531, A (Hoechst AG.), February 24, 1998 (02.24.98)

Document 5: JP, 3-287538, A (Sunstar Inc.), December 18, 1991 (12.18.91)

Document 6: JP, 7-101871, A (Lion Corporation), April 18, 1995 (04.18.95)

Document 7: JP, 11-502235, A (Gutierrez, Gilles), February 23, 1999 (02.23.99)

Document 8: 2000-344672, A (Meiji Milk Products Co., Ltd.), December 12, 2000 (12.12.00)

Document 9: WO, 01/076580, A1 (Takara Bio K.K.), October 18, 2001 (10.18.01)

[1] The inventions described in claims 1-11 do not appear to be novel based on documents 1-7 cited in the ISR.

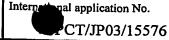
Document 1 describes that a chondroitia sulfate sodium salt is useful for bone reinforcement and osteoporosis.

Thus, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 2 describes that a sulfated saccharide is useful for matrix metalloprotease-related diseases, and the related diseases are chondropathy and other various diseases.

Thus, the inventions described in claims 1-9 of the present application do not appear to be novel.

INTERNATIONAL PRELIM RY REPORT ON PATENTABILITY



International application No. CT/JP03/15576

Box No. VI Certain documents cited

1. (Certain	published	documents	(Rule	70.10	1)
------	---------	-----------	-----------	-------	-------	----

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 02/098449 A1 [E X]	12.12.2002	03.06.2002	01.06.2001
JP 2003-26597, A [E X]	29.01.2003	11.07.2001	
Љ 2004-2375 A [E X]	08.01.2004	09.04. 2003	10.04.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure (day/month/year)

Date of written disclosure referring to non-written disclosure (day/month/year)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient. Continuation of $Box\ V$:

Document 3 describes that pectate calcium has an effect of reinforcing bones; therefore, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 4 (claim 7) describes that a polyacrylic acid is useful for a rheumatic condition; therefore, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 5 describes that a polyacrylic acid is useful for reproducing and promoting periodontal tissues; therefore, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 6 describes that various seaweed extracts are useful as an arthrosis remedy; therefore, the inventions described in claims 10 and 11 of the present application do not appear to be novel.

Document 7 describes that a Dictyotales-origin extract is useful for remedy of tissue damage of bones and cartilages, and the extract can be obtained from brown algae and the like. Thus, the inventions described in claims 10 and 11 of the present application do not appear to be novel.

[2] The inventions described in claims 1-9 do not appear to involve an inventive step based on documents 8-9 cited in the ISR.

Document 8 describes that a tannin compound is useful for intractable diseases caused by a matrix metalloprotease activity control inability, and the diseases are osteoarthrosis, bone disease and the like.

Document 8 does not disclose a chlorogenic acid. However, in addition, document 9 describes that a coffeic acid identical to a chlorogenic acid in a chemical structure is useful as a cartilage protective agent.

Thus, applying a chlorogenic acid which is a tannin compound to osteoarthrosis, bone disease and the like could be easily conceived of by a party skilled in the art.